K081265

I. 510(k) SUMMARY

Submitted By:

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OCT 16 2009

Contact Person:

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Date Prepared: April 28, 2008

Proprietary Name: None

Common Name: Male Latex Condom: Flared, 56mm (nominal width)

Classification Name: Male Latex Condom

Predicate Devices: Church & Dwight Male Latex Condom – K001212

Description of Device:

This condom is made of a natural rubber latex sheath, which completely covers the erect penis with a closely fitted membrane. This condom is colorless, smooth, flared at the closed end with a reservoir tip; nominal lay flat width 56mm, nominal length 200 mm, and nominal thickness 0.07mm. It is lubricated with silicone (viscosity 250 cps), and cornstarch is used as a dressing material. This condom conforms to current established national and international voluntary standards including ASTM D3492:2008 and ISO 4074:2002.

Intended Use of the Device:

This latex condom has the same intended use as the predicate condom. The condom is used for contraception and for prophylactic purposes to help prevent pregnancy and the transmission of sexually transmitted diseases, including HIV.

Technological Characteristics:

This condom has the same technological characteristics as the predicate condoms identified above. It is made from natural rubber latex and the design is in conformance with current versions of ASTM D3492 and ISO 4074 Male Latex Condom Standards. The Thai Nippon condom is designed with a wider width of 56mm for the man who needs a larger size condom. This condom is intended for men who feel that current regular size condoms are too small.

DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room – WO66-G609
Silver Spring, MD 20993-0002

Thai Nippon Rubber Industry
c/o Mr. Eli Carter
Consultant
Eli Carter and Associates
PO Box 12139
DURHAM NC 27709

OCT 16 2009

Re: K081265
Trade/Device Name: Thai Nippon Male Latex Condom 56mm (nominal width), flared, Colorless, silicone lubricated
Regulation Number: 21 CFR §884.5300
Regulation Name: Condom
Regulatory Class: II
Product Code: HIS
Dated: September 28, 2009
Received: October 5, 2009

Dear Mr. Carter:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical

device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Janine M. Morris
Acting Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

II. *INDICATIONS FOR USE STATEMENT*

510(k) Number: K081265

Device Name: **Thai Nippon Male Latex Condom 56mm (nominal width), flared, colorless, silicone lubricated**

Indications for Use: The Thai Nippon Male Latex Condom is used for contraception and for prophylactic purposes (to help prevent pregnancy and the transmission of sexually transmitted diseases)

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEED
Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use _____ or Over-the-Counter Use X
(Per 21 CFR 801.109)

(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K081265